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per

PTO/SB/21 (09-04)

TRANSMITTAL  
FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

189

Application Number

10/540,803

Filing Date

June 23, 2005

First Named Inventor

Green, Daniel T.

Art Unit

Unassigned

Examiner Name

Unassigned

Attorney Docket Number

022354-000310US

## ENCLOSURES (Check all that apply)

☐

Fee Transmittal Form

☐

Fee Attached

☐

Amendment/Reply

☐

After Final

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Affidavits/declaration(s)

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Extension of Time Request

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Express Abandonment Request

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Information Disclosure Statement

(2 pgs)

☐

Certified Copy of Priority Document(s)

☐

Reply to Missing Parts/ Incomplete Application

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Reply to Missing Parts under 37 CFR 1.52 or 1.53

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Drawing(s)

☐

Licensing-related Papers

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Petition

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Petition to Convert to a Provisional Application

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Power of Attorney, Revocation Change of Correspondence Address

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Terminal Disclaimer

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After Allowance Communication to TC

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Appeal Communication to Board of Appeals and Interferences

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Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)

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Proprietary Information

☐

Status Letter

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Other Enclosure(s) (please identify below):

Return Postcard

PTO/SB/08A and PTO/SB/08B (3 pgs)

References AY-BY (183 pgs)

Remarks

The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

Townsend and Townsend and Crew LLP

Signature

Printed name

Randolph Ted Apple

Date

3/15/2006

Reg. No.

36,429

## CERTIFICATE OF TRANSMISSION/MAILING

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3/15/06

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On 3/15/06

TOWNSEND and TOWNSEND and CREW LLP

By:   
Anthony J Marshall



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Daniel GREEN et al.

Application No.: 10/540,803

Filed: June 23, 2005

For: COMPOSITIONS AND METHODS  
FOR THE PREVENTION AND  
CONTROL OF INSULIN-INDUCED  
HYPOGLYCEMIA

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached PTO/SB/08A and PTO/SB/08B forms are being called to the attention of the Examiner. Copies of references AY-BY are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information, and no inference should be made that the information and references cited are, or


Daniel GREEN et al.  
Application No.: 10/540,803  
Page 2

are considered to be material to patentability because they are in this statement. No inference should be made that the information and references cited are prior art merely because they are in this statement.

Applicant believes that no fee is required for submission of this statement.

However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

  
Randolph Ted Apple  
Reg. No. 36,429

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60675489 v1



PTO/SB/08A (08-03)

|   |   |    |                          |                        |                 |
|---|---|----|--------------------------|------------------------|-----------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    | <b>Complete if Known</b> |                        |                 |
|   |   |    | Application Number       | 10/540,803             |                 |
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|   |   |    | First Named Inventor     | Green, Daniel T.       |                 |
|   |   |    | Art Unit                 | Unassigned             |                 |
|   |   |    | Examiner Name            | Unassigned             |                 |
| Sheet   | 1 | of | 3                        | Attorney Docket Number | 022354-000310US |

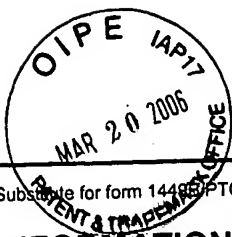
| U.S. PATENT DOCUMENTS+ |                          |  |                                |  |   |
|------------------------|--------------------------|--|--------------------------------|--|---|
| Examiner<br>Initials*  | Cite<br>No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                        |                          | Number Kind Code <sup>2</sup> (if known) |                                |  |   |
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|                        | AD                       | US-6,461,331                             | 10-08-2002                     | Van Antwerp  |   |
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|--------------------------|-----------------------|---------------------------|---------------------|-----------------------------------|--------------------------------|--|--|--------------------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   |                     |                                   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup>           |
|                          |                       | Country Code <sup>3</sup> | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |                                |  |  |                          |
|                          | AY                    | WO                        | 02/43566            | A2                                | 06-06-2002                     |  |  | <input type="checkbox"/> |
|                          | AZ                    | GB                        | 748857              |                                   | 05-09-1956                     |  |  | <input type="checkbox"/> |
|                          | BA                    | GB                        | 844434              |                                   | 08-10-1960                     |  |  | <input type="checkbox"/> |
|                          | BB                    | GB                        | 831907              |                                   | 04-06-1960                     |  |  | <input type="checkbox"/> |
|                          | BC                    | GB                        | 766994              |                                   | 01-30-1957                     |  |  | <input type="checkbox"/> |
|                          | BD                    | GB                        | 766995              |                                   | 01-30-1957                     |  |  | <input type="checkbox"/> |

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| Examiner<br>Signature |  | Date<br>Considered |  |
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PTO/SB/08B (08-03)

|  |   |    |                          |                        |                 |
|--|---|----|--------------------------|------------------------|-----------------|
| Substitution for form 1449B PTO<br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(use as many sheets as necessary) |   |    | <b>Complete if Known</b> |                        |                 |
|  |   |    | Application Number       | 10/540,803             |                 |
|  |   |    | Filing Date              | June 23, 2005          |                 |
|  |   |    | First Named Inventor     | Green, Daniel T.       |                 |
|  |   |    | Art Unit                 | Unassigned             |                 |
|  |   |    | Examiner Name            | Unassigned             |                 |
| Sheet  | 2 | of | 3                        | Attorney Docket Number | 022354-000310US |

| NON PATENT LITERATURE DOCUMENTS |                       |   |                                     |  |
|---------------------------------|-----------------------|---|-------------------------------------|--|
| Examiner Initials *             | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup>                      |  |
|                                 | BE                    | ABS et al., "Hypoglycemia owing to inappropriate glucagons secretion treated with a continuous subcutaneous glucagons infusion system," <i>Acta Endocrinol. (Copenh)</i> , 122(3):319-322 (1990).   | <input type="checkbox"/>            |  |
|                                 | BF                    | ATVALL et al., "Insulin-antagonistic effects of pulsatile and continuous glucagons infusions in man--a comparison with the effect of adrenaline," <i>J. Clin Endocrinol. Metab.</i> , 74(5):1110-1115 (1992).   | <input type="checkbox"/>            |  |
|                                 | BG                    | AYNSLEY-GREEN et al., "Nesidioblastosis of the pancreas: definition of the syndrome and the management of the severe neonatal hyperinsulinaemic hypoglycaemia," <i>Arch. Dis. Child.</i> , 56(7):496-508 (1981).  | <input type="checkbox"/>            |  |
|                                 | BH                    | BERGMAN et al., "Central role of the adipocyte in the metabolic syndrome," <i>J. Investig. Med.</i> , 49(1):119-126 (2001).   | <input type="checkbox"/>            |  |
|                                 | BI                    | BOLLI et al., "Nocturnal blood glucose control in type I diabetes mellitus," <i>Diabetes Care</i> , 16(suppl. 3):71-89 (1993).  | <input type="checkbox"/>            |  |
|                                 | BJ                    | BRATUSCH-MARRIAN et al., "The role of 'diabetogenic' hormones on carbohydrate and lipid metabolism following oral glucose loading in insulin dependent diabetics: effect of acute hormone administration," <i>Diabetologia</i> , 21(4):387-393 (1981).          | <input type="checkbox"/>            |  |
|                                 | BK                    | BRAY, G.A., "The Zucker-fatty rat: a review," <i>Fed. Proc.</i> , 36(2):148-153 (1977).   | <input type="checkbox"/>            |  |
|                                 | BL                    | BREMER et al., "Protein delivery with infusion pumps," <i>Pharm. Biotechnol.</i> , 10:239-254 (1997).   | <input type="checkbox"/>            |  |
|                                 | BM                    | CEDERBLAD et al., "Effect of glucagons on glucose production, lipolysis, and gluconeogenesis in familial hyperinsulinism," <i>Horm. Res.</i> , 50(2):94-98 (1998).  | <input type="checkbox"/>            |  |
|                                 | BN                    | CHRISTIANSEN et al., "Zinc-protamine-glucagon in the treatment of Paget's disease of bone. Preliminary Report," <i>Acta Med. Scand.</i> , 196(6):495-496 (1974).  | <input type="checkbox"/>            |  |
|                                 | BO                    | CLARKE et al., "The effect of hyperglucagonemia on blood glucose concentrations and on insulin requirements in insulin-requiring diabetes mellitus," <i>Diabetes</i> , 27(6):649-652 (1978).  | <input type="checkbox"/>            |  |
|                                 | BP                    | CRYER et al., "Hypoglycemia in Diabetes," <i>Diabetes Care</i> , 26(6):1902-1912 (2003).  | <input type="checkbox"/>            |  |
|                                 | BQ                    | DAY et al., "Depot-glucagon in the treatment of McArdle's disease," <i>Aust N.Z. J. Med.</i> , 15(6):748-750 (1985).  | <input type="checkbox"/>            |  |
|                                 | BR                    | HAYMOND et al., "Mini-Dose Glucagon Rescue for Hypoglycemia in children With Type 1 Diabetes," <i>Diabetes Care</i> , 24(4):643-645 (2001).   | <input type="checkbox"/>            |  |
|                                 | BS                    | IVKOVIC-LAZAR, T., "Development and differentiation of adipose tissue," <i>Med. Pregl.</i> , 56(3-4):142-145 (2003), abstract, article in Croatian.   | <input checked="" type="checkbox"/> |  |
|                                 | BT                    | KALIMA et al., "The effect of zinc-protamine-glucagon in acute pancreatitis," <i>Ann. Chir. Gynaecol.</i> , 69(6):293-295 (1980).   | <input type="checkbox"/>            |  |

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| Examiner Signature |  | Date Considered |  |
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|                                 | BU                       | KOLLEE et al., "Persistent neonatal hypoglycaemia due to glucagons deficiency," <u>Arch Dis. Child</u> , 53(5):422-424 (1978).  | <input type="checkbox"/> |
|                                 | BV                       | NICOLAIDIS, S., "Physiology of food intake and regulation of body weight," <u>Ann. Endocrinol.</u> , 49(2):89-97 (1988) abstract, article in French..   | <input type="checkbox"/> |
|                                 | BW                       | PICHLER et al., "Haemodynamic effects of depot zinc protamine glucagons in heart failure," <u>Wein Klin Wochenschr.</u> , 91(2):49-51 (1979) abstract only, article in German.  | <input type="checkbox"/> |
|                                 | BX                       | SCHMID et al., "McArdle's disease: therapeutic use of depot-glucagon," <u>Dtsch Med. Wochenschr.</u> , 107(47):1809-1811 (1982) abstract only, article in German.   | <input type="checkbox"/> |
|                                 | BY                       | TRADING et al., "Bioogical and Chemical Properties of Two Glucagon Preparations with Prolonged Action," <u>Eur. J. Pharmacology</u> , 7:206-210 (1969).   | <input type="checkbox"/> |
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